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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,771	08/25/2006	Michael S. Kinch	10271-131-999	2188

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JONES DAY
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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
09/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,771	KINCH, MICHAEL S.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/25/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-24 are pending.

Claims 1-24 are examined on the merits.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-12, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 2004/045544 A2 (effective filing date 19 November 2002). The WO document discloses on page 16 of the document,

> [0043] Anti-PCDGF receptor antibodies are capable of binding to tumorigenic cells but not to normal cells. As shown in FIG. 7, anti-PCDGF receptor antibodies bind strongly to breast cancer tissue (panels B and C) but not to normal tissue (panel A) in an immunostaining protocol using 10 micrograms/ml of 6G8 anti-PCDGF receptor antibody. Thus, anti-PCDGF receptor antibodies can also be used to diagnose tumorigenicity by comparing the level of PCDGF receptor in a tissue sample or biopsy to the level of PCDGF receptor in normal tissue. Elevated levels of PCDGF receptor indicate the cells are tumorigenic.

The claimed invention is also disclosed in claims 38-47. The said antibody, including humanized antibodies contact tumorigenic cells such as cells derived from blood, urine, nipple aspirate, prostate, neural and lung via immunoassays, see page 7, section 0024; page 12, section 0034; page 13, section 0035; page 16, section 0044.

4. Claims 1-24 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 2005/000207 A2 (effective filing date May 30, 2003/ IDS reference B06 submitted August 25, 2006). The WO document discloses the detection and diagnosis of a disease or disorder associated with aberrant expression of a polypeptide, such as PCDGF in the cells or body fluid of an individual using classical immunohistological methods, see page 49, line 4-page 50, line 26. The antibodies of the invention used in disclosed diagnostic methods include human antibodies, as well as humanized, see

page 16, lines 3-21. "PCDGF is overexpressed in a number of tumor cell types…", hence assaying a number of cancers, hyperproliferative disorders, as well as precancerous disorders was implemented, see page 35, line 16-page 39, line 16.

5. Claims 1-12, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2003/0108950 A1 (filed October 28, 2002/ IDS reference A10 submitted August 25, 2006). Publication number 2003/0108950 discloses diagnosing tumorigenicity by measuring the concentration of GP88 in blood, plasma, serum, saliva, urine, needle biopsies from breast cancer patients, as well as other biological fluids detected by immunoassay methods including the use of antibodies, see abstract; page 8, section 0099-page 9, section 0106. GP88 is art known to as 88 kDa glycoprotein PC cell-derived growth factor (PCDGF/GP88), also known as progranulin.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2004/045544 A2 (effective filing date 19 November 2002), and further in view of WO 2005/000207 A2 (effective filing date May 30, 2003/ IDS reference B06 submitted

August 25, 2006). The teachings of WO 2004/045544 A2 have been presented in the 102(e) rejection. That WO document does not teach the claimed method, wherein the presence of PCDGF or PCDGF receptor is detected in particular pre-cancerous conditions listed in claims 13-23.

However, WO 2005/000207 A2 teaches numerous precancerous and hyperproliferative conditions which PCDGF is overexpressed, see page 35, line 16-page 36, line23. These conditions include fibrocystic disease, cervix dysplasia, adenomatous polyps, Barrett's esophageal dysplasia, adenomatous hyperplasia, atypical adenomatous hyperplasia, pancreatic hyperproliferative disorders, prostatic intraepithelial neoplasia and xeroderma pigmentosum. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to assay conditions that are cancer-related. One of ordinary skill in the art would have been motivated to do so because "PCDGF is [art known to be] a highly tumorigenic autocrine growth factor and causative agent for a wide variety of tumors", see page 5 of WO '000207.

8. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2003/0108950 A1 (filed October 28, 2002/ IDS reference A10 submitted August 25, 2006), and further in view of WO 2005/000207 A2 (effective filing date May 30, 2003/ IDS reference B06 submitted August 25, 2006). The teachings of the publication have been presented in the 102(e) rejection. The publication does not teach the claimed method, wherein the presence of PCDGF or

PCDGF receptor is detected in particular pre-cancerous conditions listed in claims 13-23.

However, WO 2005/000207 A2 teaches numerous precancerous and hyperproliferative conditions which PCDGF is overexpressed, see page 35, line 16-page 36, line23. These conditions include fibrocystic disease, cervix dysplasia, adenomatous polyps, Barrett's esophageal dysplasia, adenomatous hyperplasia, atypical adenomatous hyperplasia, pancreatic hyperproliferative disorders, prostatic intraepithelial neoplasia and xeroderma pigmentosum. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to assay conditions that are cancer-related. One of ordinary skill in the art would have been motivated to do so because "PCDGF is [art known to be] a highly tumorigenic autocrine growth factor and causative agent for a wide variety of tumors", see page 5 of WO '000207.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
04 September 2008
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643